# MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

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### *Abstract*

We are developing a new class of implantable electronic devices for a wide range of neural prosthetic applications. Each implant consists of a microminiature capsule that can be injected into any desired location in the body through a 12 gauge hypodermic needle. Multiple implants receive power and digitally-encoded command signals from an RF field established by a single external coil. The first two types of implant that we have made were single-channel microstimulators equipped with either a capacitor-electrode or an internal capacitor that stores charge electrolytically and releases it as current-regulated stimulation pulses upon demand. We are also working on implants equipped with bidirectional telemetry that can be used to record sensory feedback or motor command signals and transmit them to the external control system.

In this quarter, we continued development of the glass capsule using glass-to-tantalum seals at both ends. We identified the likely cause of the progressive hermeticity failures with the glass-to-PtIr seals, now abandoned in favor of glass-to-Ta seals at both ends of the glass capsule. These studies have now led to an improved packaging design.

## *Hermetic Packaging Development at Queens and AEMF*

### *Glass-to-PtIr Seals*

The coefficient of thermal expansion of the borosilicate glass that we are using for the capsule is fairly well matched to tantalum but it is substantially lower than that for PtIr. Empirically, however, we found that when heated adequately during the sealing process, the glass around the PtIr tube exhibited a fairly high level of compression as measured by photoelastic stress and this compression was associated reliably with seals that tested hermetic at the limits of our Alcatel helium leak tester (approximately $2 \times 10^{-11}$ cc He atm/s).

BIONs made with glass-to-PtIr seals started failing during chronic testing in our high temperature saline bath, often considerably faster than could be accounted for by residual leaks below our detection limit during production tests. (However, one such BION has now been on continuous testing for over 9 months with no signs of failure, even though we omitted the moisture getter to accelerate failure from any incoming moisture.) During post mortem testing, leaks on the order of $10^{-9}$ were traced to the PtIr end of the capsule. Photoelastic stress measurements showed very low compression levels, similar to those associated in the past with inadequate laser sealing schedules that were known to produce such leaks. Unfortunately, we did not have any photoelastic stress measurements from these devices at the time of their manufacture, when there were also substantial questions about the control of the laser itself. We did, however, locate a number of scrap parts from this period that had been stored in air that showed the expected high levels of compressive stress. This led to the seemingly unlikely hypothesis that water might somehow interact with the seals to relieve the glass stress. This was tested by soaking the high-stress scrap parts in saline for a few days and repeating the photoelastic stress measurements. The high stresses disappeared, resulting in photoelastic patterns similar to the devices that had failed during soak testing and confirming this hypothesis.

It is difficult to imagine water permeating borosilicate glass in this period of time in order to relieve stress stored in the crystalline structure deep in the glass bead. An alternative hypothesis is that we have been misinterpreting the photoelastic stress patterns all along. Consider a glass-to-PtIr seal in which there is substantial adhesion between the glass and the PtIr but the PtIr is trying to shrink away from the glass (which is what would be expected for this particular mismatch of thermal coefficients). This would result in tensile stress in the glass perpendicular to the PtIr but compressive stress in the circumferential direction (akin to hanging a weight from the center of an archway), thus accounting for the compression noted in the photoelastic stress measurements. In a dry state, the free energy of the adhesive bond between the glass and the PtIr could resist the tensile force and maintain hermeticity. Water is a polar solvent, however, which is ideally suited to lowering adhesive free energy by insinuating itself into bonds (we have seen this both with electrostatic bonds such as in metal thin films on dielectric substrates and with covalent bonds such as in hydrolysis of stressed polyimide in water). The water would enter the interface between the glass bead and the PtIr tube at the outside end of the seam and rapidly unzip the adhesion as it diffused along the opening seam. This would relieve all of the stresses in the glass and result in a relatively large leak where none had been detected before.

### ***Glass-to-Tantalum Seals***

In our last QPR (#10), we presented the electrochemical test results that demonstrated the safety of using a Ta feedthrough with the Ir electrodes, replacing the PtIr tube. Thus, both ends of the capsule can utilize glass-Ta seals, which have a long history of high yields and successful hermeticity with low stress for a wide range of weld schedules. The robustness of these seals is probably due to chemical bonding between the glass and the stable native oxide of tantalum plus the much closer match in thermal coefficient of expansion between N51A glass and Ta than with Pt10Ir.

In this quarter, we obtained Ta tubes with various dimensions and adapted the various associated components and weld schedules to this new strategy. Our approach is to simplify the fabrication of this subassembly and the electromechanical connection to the electronic subassembly by using the following sequence:

1. Resistance weld gold-plated elgiloy spring to end of Ta tube - successfully completed.
2. Melt glass bead onto Ta tube - see below
3. Close capsule by CO2 laser melting glass capillary to glass bead on Ta tube - successfully completed.
4. Seal capsule and attach Ir electrode in one step with YAG laser weld - successfully completed, but will require fine-tuning after completing other steps.

The nature of the oxide that forms on the Ta is important for the hermeticity of the glass-to-Ta seals. The Ta wire stems on the sintered Ta electrodes have a native oxide that seals well to glass beads in an argon atmosphere; sealing in air can produce excess oxide that appears to be porous, resulting in slow leaks. We obtained three batches of Ta tubes with different dimensions but had difficulty producing consistently hermetic seals to any of them. A wide variety of weld schedule parameters were investigated in an attempt to adjust for differences in heat capacity, heat-sinking and surface oxide conditions, including attempts to build up various surface oxide layers by omitting the argon curtain during sealing or by preanodizing or prebaking the Ta tubes. Reviews with experts in this field revealed that small amounts of impurities in the tantalum are known to interfere with the integrity of the oxide layer. It has been hypothesized that these impurities are causing the problem with the glass-to-tube seals. We are now waiting for new Ta tubes to be made from a purer grade of Ta.

### *Medical Imaging at Queens*

One important aspect of clinical use of injectable microstimulators is their compatibility with various imaging techniques that might be useful to locate the devices themselves and to obtain noninvasive morphometry of the stimulated muscles.

In a first experiment, we implanted a single microstimulator into the hip of a fresh, 80 kg pig cadaver and subjected it to magnetic resonance (MR), computed x-ray tomography (CT) and ultrasound (US) imaging. The device was easily located in all three, producing a bright contrast spot in US, a fairly detailed image in CT, and a bright image surrounded by a light and dark ghosts extending several centimeters around the implant in MR. The borders between muscles were about equally well-resolved with MR and CT, although the ghosts interfered more in MR. In the US images, it was still possible to locate the muscle borders but this required more careful alignment of the probe head, which is held manually, in order to reconcile them with the known anatomy of the specimen.

In a second experiment, we compared US to CT using a spaced array of 6 devices injected in a row into a similar porcine hip. The US images were aligned by marks on the surface of the skin and all devices were easily located. A clinical consultant concluded that US imaging could be used to locate devices and guide their surgical removal if necessary, obviating the need for ionizing radiation or a special sensing probe. The muscle morphometry from the US and CT images is in the process of being compared for reproducibility by having them quantified by staff who are unfamiliar with the specimen and imaging sessions.

### *Integrated Circuit Development at AEMF and Pritzker*

The revised ASIC has arrived from the foundry, but definitive tests will not be available until next quarter. The switch to N-well from P-well CMOS and required redesign of component sequence in the internal package. The end of the μPCB that contacts the Ir electrode feedthrough is shaped with electroplated notches spaced to accommodate the ends of the elgiloy spring. The other end is notched and plated to connect electromechanically to the PtIr washer on the Ta stem or to the internal electrolytic capacitor.

During the last quarter work at the Pritzker Institute focussed on two areas, layout revision of the microstimulator ASIC to reduce its length, and revision of the on-chip rectifier/telemetry module for the bidirectional telemetry micromodules.

#### *Microstimulator Layout Revision*

Since April of 1997, we have been using PC-based and UNIX-based CAD tools to perform layout at IIT. This effort has been highly successful and has allowed for a complete "design to fabrication ready" process at IIT. We have used these new capabilities on a number of research programs.

Circuit defects, identified by the Mann Foundation, in the microstimulator ASIC were given to IIT for implementation on the microstimulator ASIC layout. In addition, we proposed reducing the length of the layout to permit fabrication on a MOSIS small recticle, since the cost of the small recticle is about 30% that of the large recticle, previously used. This reduction in length impacted only the available power-supply capacitance. Test showed that the needed capacitance was less than the that which could be placed into the shorter layout. Therefore we reduced the length of the microstimulator ASIC and implemented the required circuit changes. This new layout was delivered to the Mann Foundation for examination and submittal for fabrication.

***Rectifier Analysis***

Most of our efforts, this quarter, were spent in examining a new prototype MOSIS ASIC, MOS4. MOS4 was submitted in October, 1997 and implemented the guard-band structure shown in Figure 2 below. By way of review, this guard band structure was designed to interrupt the parasitic current in a combined horizontal-vertical bipolar transistor structure, described in our last report.

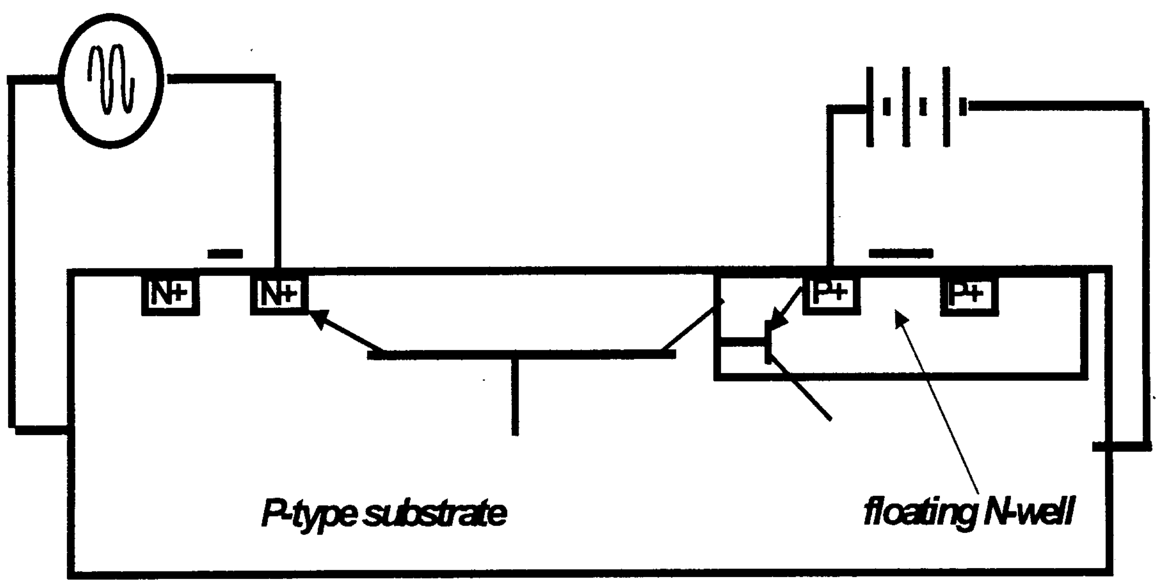



Figure 1 - Depiction of horizontal and vertical-parasitic bipolar transistors in MOS1

Figure 1, above, reviews the structure of the parasitic bipolar problem seen in MOS1. Figure 2, below, depicts the solution which we implemented in MOS4.

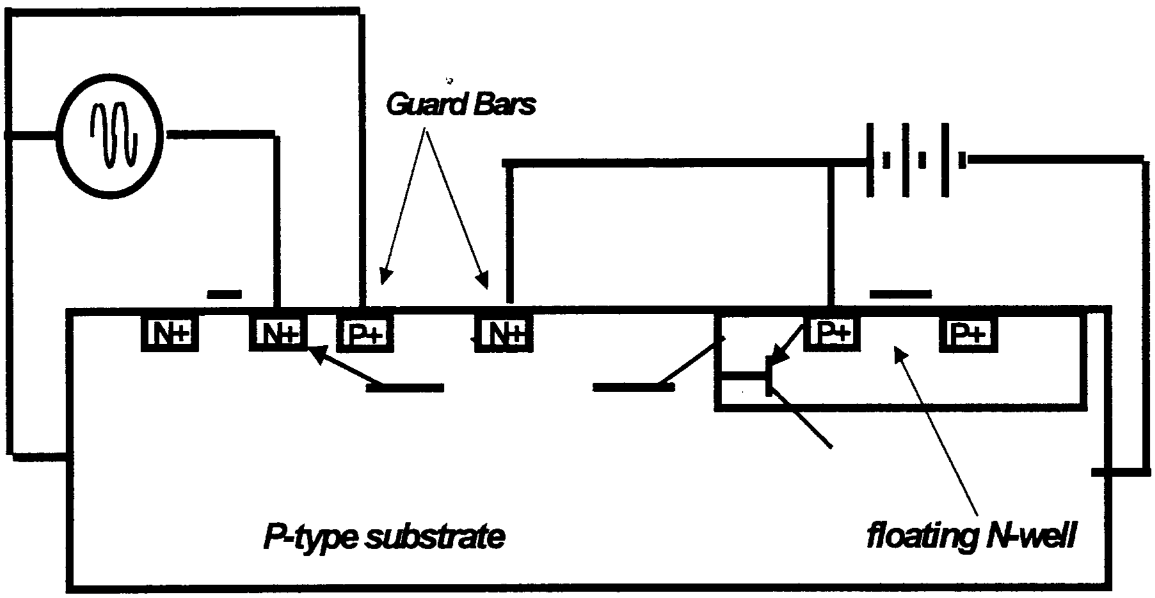



Figure 2 - Guard-Band structure implemented in MOS4

Unfortunately, this guard structure did not solve the parasitic problem. In addition, the bridge design in MOS4 used newly-sized transistors for the lower rectification elements which caused increased current to flow in the parasitic transistors.

Upon delivery, MOS4 was analyzed for parasitic current. Measurements showed that the parasitic effects were not reduced from that which we had measured in MOS1. We then spent considerable time measuring MOS4 using a combination of laser trace cutting, internal circuit probing, and curve tracer measurements. The layout used 16 sequential substrate and power supply guard-bands to isolate the floating well from the substrate current of the lower rectifier N-Fets.

To some degree, the guard-bands did isolate the floating well. However, this isolation was not effective in preventing the substrate current from reaching other wells, which were part of the guard structures and connected to the power supply. We did confirm that the gain of the horizontal NPN transistor was less than 1, about 0.8. However, even a gain of less than unity results in excessive power-supply-to-substrate currents. Consider that the rectification current which flows in the N+/Psubstrate junctions is also emitter current for the NPN transistor, as shown in Figure 3, below. Collector current, in the NPN transistor, causes power-supply-to-substrate current to flow. Transistor gain rises with increasing collector current. When the collector current of the parasitic NPN transistor plus the ASIC power supply load current equals the maximum available current from the bridge source (implant coil), the power supply no longer increases no matter what the level of source current to the bridge. For MOS4 this value was about 4 volts.

Since the guard-band structure consisted of alternating substrate diffusions and N-wells, we had guarded the floating well, at the expense of creating more NPN parasitic transistors. In retrospect the creations of these new transistors was obvious. However, our attention was focussed upon diverting the current from the floating well. Previously we did not appreciate the impact of the horizontal NPN transistor alone, even though its gain is unity or below. Although we did create these new parasitic transistors, this structure was an improvement over the MOS1 structure in which substrate current reached the floating well. Substrate current which reaches the floating well is further multiplied by the gain of the vertical PNP parasitic transistor contained within the well.

However, the improvement is insufficient to avoid a significant drain on the power supply. This situation is shown in Figure 3, below.

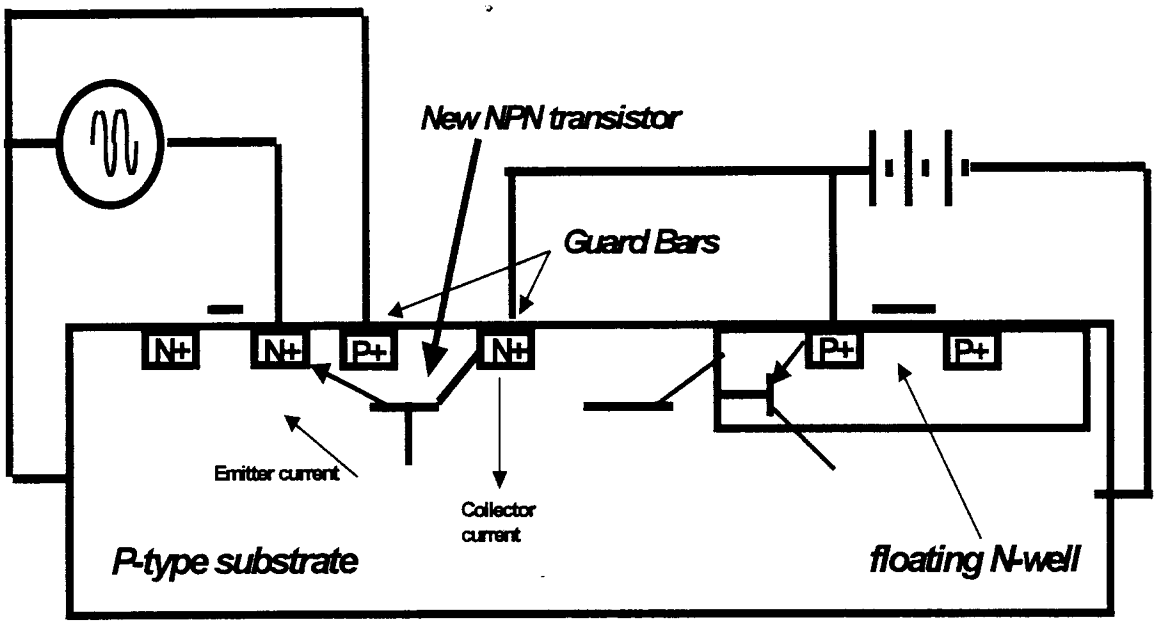



Figure 3 - New parasitic transistor created by addition of guard bands. Although substrate current is blocked from the floating well, the new transistor causes a drain on the Power Supply.

We expended much effort to understand the precise mechanisms of the new parasitic bipolars, to measure their gain, and to understand the geometric significance of the spacing between the guard-bands. Based upon these measurements we have identified a new strategy for which we have extremely high confidence. The MOS4 design used synchronous rectification for the upper P-Fet rectifiers. We now intend to use synchronous rectification on the lower N-Fet rectifiers, and increase the size of the N-Fets so that during conduction the forward voltage drop across these N-Fet rectifiers will be so low that no significant current will flow through the emitter-base junction of the parasitic NPN. This is the strategy shown in the Figure 4, below. In addition, we have used one large substrate guard-band surrounding the rectifier N-Fets, and one large N-Well guard-band surrounding the rectifier P-Fets.

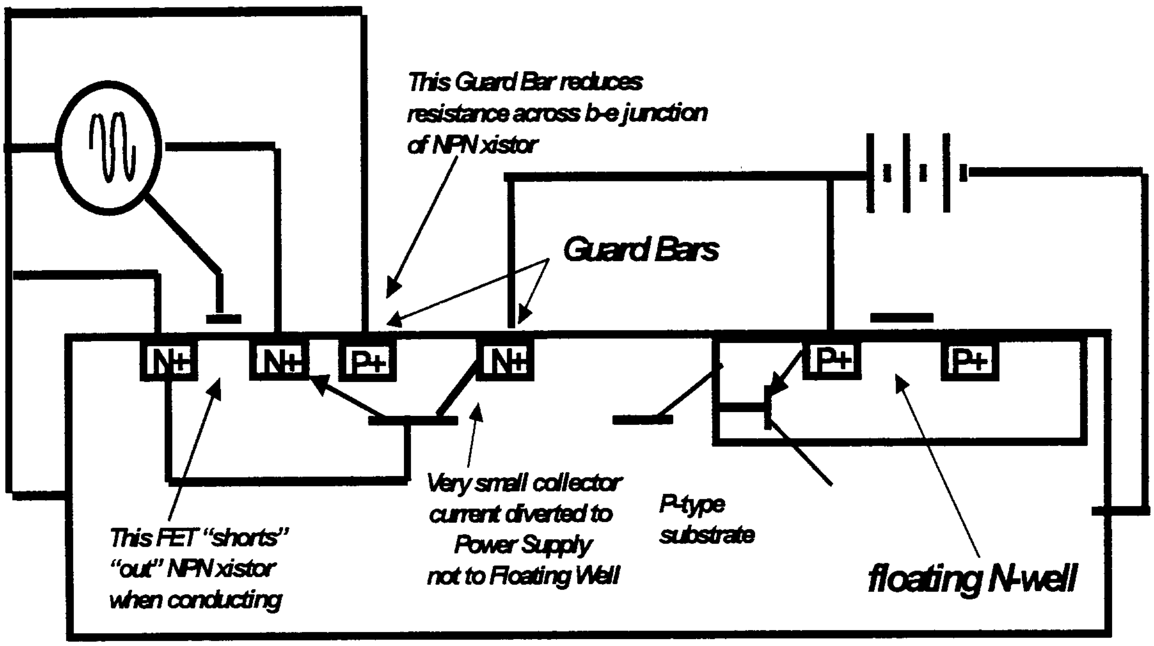
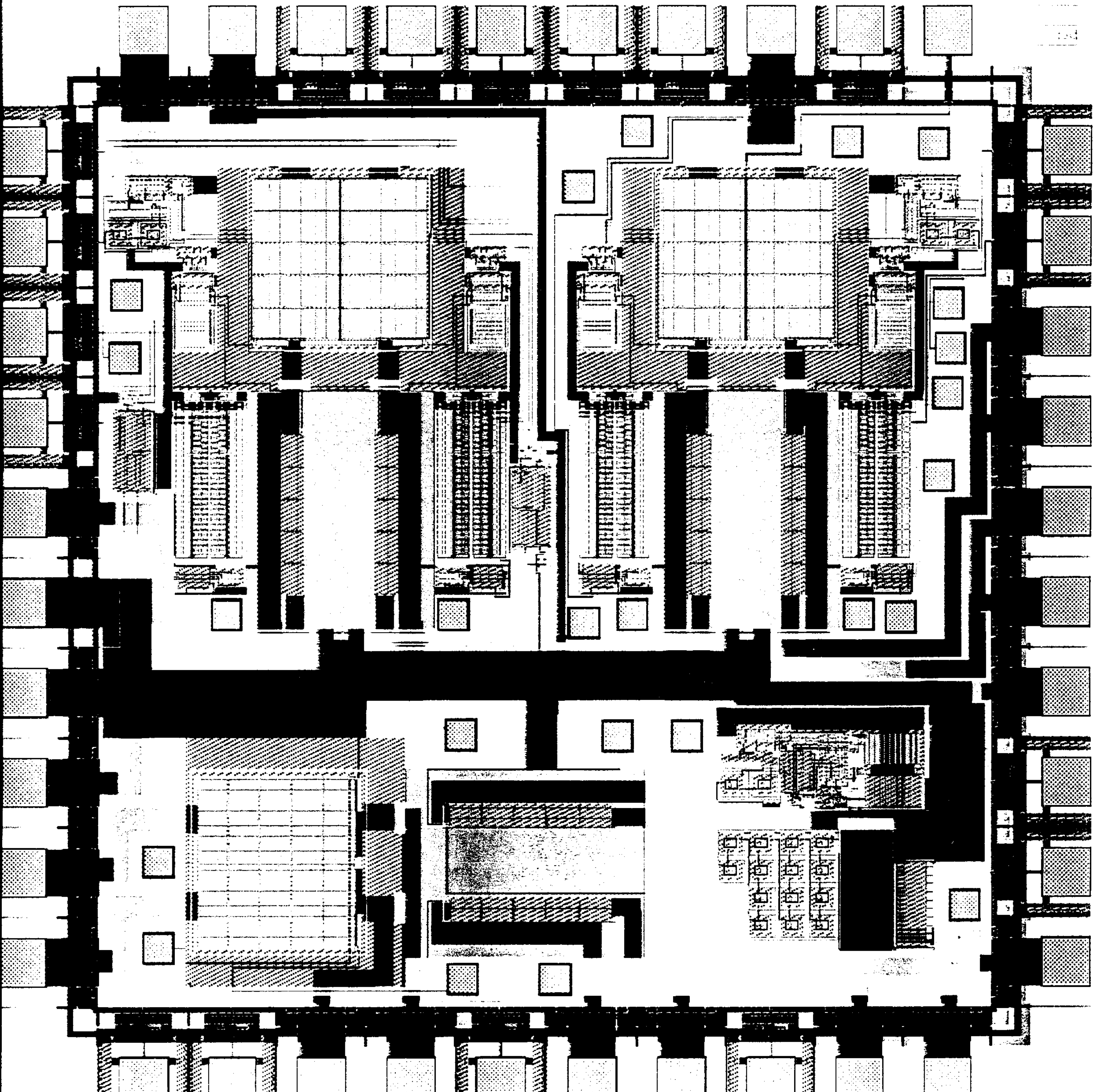



Figure 4 - New strategy for eliminating parasitic rectifier current. When the N-Fet is conducting, the voltage drop across the b-e junction of the NPN is insufficient place it into conduction.

A layout for this new chip, MOS7, has been completed and is ready for submission. We have also included the inward telemetry data detection, the clock recovery, and the local oscillator for outward data telemetry. A color plot of this layout can be seen in Figure 5, below.



During the next quarter we expect to receive the MOS7 chips back for analysis, and we expect to complete the new electrical measurements to confirm that the parasitic problem is solved.

### *Plans*

Work planned for next quarter includes:

- Obtain electrical test results on new stimulator ASIC
- Build microstimulators using new ASIC and improved packaging techniques
- Encapsulate and begin qualification testing of microstimulators and dummy circuits in revised packages
- Obtain components and subassemblies, develop assembly procedures and begin qualification testing of microstimulators in improved packages